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[REDACTED] EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/490,345	LUEDTKE ET AL.
	Examiner	Art Unit
	Ashwin Mehta	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,4-10,15,16,21,23-27,37-43 and 52-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1,2,4,5,7,21,23,24,26,27 and 40 is/are allowed.

6) Claim(s) 6, 9, 10, 15, 16, 25, 37-39, 41-43, and 52-59 is/are rejected.

7) Claim(s) 8 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 14, 17, 33, 36, 41, 43, 45, and 46 under the judicially-created doctrine of obviousness-type double patenting is withdrawn, in light of the claim amendments and cancellations.
3. The rejections of claims 3, 5, 14, 22, 33, 40-46, 50, and 51 under 35 U.S.C. 112, 2nd paragraph, are withdrawn, in light of the claim amendments or cancellations.
4. The rejection of claims 14, 17, 33, 36, 41, 43, 45, and 46 under 35 U.S.C. 102(e)/103(a) is withdrawn, in light of the claim cancellations or amendments.

Specification

5. The amendment filed 10 March 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: Table A inserted on page 15 after line 16. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

6. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 8 attempts to limit the method claim 7 by requiring the inbred maize plant to be the female or male parent of the cross. However, there are no other options available for the inbred maize plant in the method of claim 7.

Claim Rejections - 35 USC § 112

7. Claims 6, 25, 52-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6 and 25: the recitation “capable of expressing” in line 2 renders the claim indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation be replaced with --and having--.

In claims 52-59: the recitation “PH3PG” in claims 52-54 and 56-58 render the claims and those dependent thereon indefinite. Since the name “PH3PG” is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name “PH3PG” does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed

invention. The name appears to have been arbitrarily assigned and the specific characteristics associated therewith could be modified. Amending claims 52 and 54 to recite the ATCC deposit number in which seed of corn inbred line PH3PG has been deposited would overcome the rejection.

In claim 53: the claim recites "The backcross conversion PH3PG maize plant of claim 52" in line 1. However, claim 52 is directed to a method, not a plant.

In claim 57: the claim recites "The transgenic PH3PG maize plant of claim 56" in line 1. However, claim 56 is directed to a method.

6. Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 52-56 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 09 October 2002 under item 10. Applicant traverses the rejection in the paper filed 10 March 2003. Applicant's arguments were fully considered but were not found persuasive.

Regarding claims to transgenic PH3PG, PH3PG comprising backcross conversions, and new claims 52-59, Applicants argue that examples of transgenes, genes and traits that can be backcrossed into the PH3PG are given in the specification, and that in order to expedite prosecution, new claims 53 and 57 list the type of traits that may be conferred by backcross conversions and transgenes (response, paragraph bridging pages 13-14). However, claims 52

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and 56 do not list the types of genes contemplated, and the effect on the description of the plant produced is unknown. Further, the specification does not describe any plants that were produced by backcrosses that are exactly the same as PH3PG except for the introduced gene. Applicants argue that breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses, and cite Openshaw et al. for support (response, paragraph bridging pages 13-14). However, Table 1 in the reference appears to indicate that only 87.5% of the recurrent parent genome is recovered after two backcrosses, and only assuming that there is no linkage to the gene being transferred. Further, the results referred to by Applicants were of computer simulations. Real field data showed that the recovery of the recurrent parent was lower after two backcross generations (page 42). Furthermore, the computer simulations of Openshaw et al. assume the absence of linkage of the allele being transferred from the donor parent. Moreover, even if 98% genome identity were obtained between the backcross conversion and recurrent parent, the remaining 2%, given the size of the maize genome, would encode traits not described by the specification. The specification also does not describe other nonselected traits and genes transferred during the first cross, and which are not selected out. Furtherstill, the instant disclosure did not describe any molecular marker data for PH3PG at the time of filing. Applicant cites Wych for teaching that the backcrossing has been used since the 1950s, Poehman et al. for teaching that a backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene (response, paragraph bridging pages 14-15). However, neither reference indicates that the plant comprising the single gene conversion is exactly the same except for the added gene.

Regarding claims 9 and 10: Applicants note that a claim to a F1 hybrid made with a deposited inbred was expressly acknowledged by the United States Supreme Court in J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc. (response, paragraph bridging pages 15-16). However, that case concerned issues under the utility guidelines of 35 U.S.C. 101, not written description. Applicants argue that one of ordinary skill in the art would be able to run a molecular profile on PH3PG and an F1 hybrid and be able to identify the F1 hybrid as being produced from PH3PG, and that seed pericarp tissue can be used to discern the maternal or paternal origin of the allele sets if necessary (paragraph bridging pages 15-16). However, SSR and RFLP data were not described in the specification as originally filed. Further, Applicants do not correlate any functions with any SSR or RFLP markers. One skilled in the art cannot correlate any traits expressed by the claimed plants with any molecular markers. Moreover, Applicant does not describe the genotypic or phenotypic contribution from the other parent, and hence the broad claim to all F1 hybrid plants produced from the disclosed inbred parent lack adequate written description. Applicants argue that SSR and RFLP techniques can be used to analyze F1 hybrids and determine if one of its parents is PH3PG and cite Berry et al. for discussing the probability of identifying the parents of a hybrid by SSR data when neither parent is known (response, page 16, 1st full paragraph). However, choices of possible parents were provided in the article. Further, the originally filed specification does not describe any SSR, RFLP, or any other molecular markers that are unique to PH3PG. It is also noted that Berry et al. was published after the filing date of the instant application, and cannot be relied upon by Applicants for support.

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Regarding claims 15 and 16, Applicant argues that anyone of skill in the art would know how to utilize the well-established breeding methods with PH3PG (response, page 16, 2nd full paragraph). However, the claimed method requires the use of descendants of PH3PG, which are not described. A method is not fully described if components required for the method are not described. Applicants argue that claim 41 is drawn to the F1 plant produced by the method of claim 40, and is identifiable through both breeding records and molecular marker techniques, as discussed (response, paragraph bridging pages 16-17). However, breeding records and markers do not describe the morphological and physiological traits expressed by the F1 plants. Applicant argues that claim 42 is drawn to the method of selfing the F1 for successive filial generations, and claim 43 is drawn to plants derived from that method that have at least 50% of their genetics derived from PH3PG (response, paragraph bridging pages 16-17). As discussed, if all of the components needed for claimed methods are not described, the method is not described. The F1 plants need for the method of claim 42 is not described. The traits expressed by the plants of claim 43 are not described, and are not correlated with any markers from PH3PG.

Applicants argue that characterization of a plant by its parental lines is a means of description used by all breeders of ordinary skill in the art (response, paragraph bridging pages 18-19). However, it is noted that Applicants have not described all of the parents of all of the claimed hybrids. Applicants further argue that seed of PH3PG has been deposited, which allows one to test material they desire to use to determine if it is PH3PG, and that a molecular profile of line PH3PG is supplied in a declaration signed by Dr. Dinakar Bhatramakki (an employee of the assignee of the instant application). Applicants argue that the specification has also been amended to include the SSR profile of PH3PG that is supplied in the declaration. Applicants

argue that this is not new matter, as it is an inherent feature of PH3PG, which has been deposited with the ATCC. Applicants cite *Ex parte Marsili, Rosetti, and Pasqualucci* in support, stating that in *Marsili*, the Patent and Trademark Office Board of Appeals concluded that the products described had and have now the structure given in the amendment in question, and the changes made in the amendment do not constitute new matter (response, paragraph bridging pages 18-19). However, the issue in *Marsili* is not analogous. On page 905 of *Marsili*, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a correction of a previously submitted description of a compound, which is permissible. In the instant amendment, however, the newly introduced SSR data represents newly added data, and is not merely a correction of existing data. The addition of new characteristics remains impermissible. In *Marsili*, the specification disclosed a chemical structure for a compound, and the amendment merely corrected an error in the structure. In the instant case, no SSR data was present in the original specification, and the newly presented SSR data represents new matter.

Applicants also argue that the test of written description is not whether the morphological and physiological traits of the PH3PG progeny are described, but whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. Applicants continue, arguing that while PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions, and transgenic conversions to be within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner (response, paragraph bridging pages 19-20). However, the originally filed specification only

describes the deposited inbred line in terms of its morphological and physiological traits, not its genotype. As information concerning the genome of PH3PG was not known at the time of filing, molecular information cannot be used to describe progeny of PH3PG. Further, as Applicant admits, the requirements for PVP and patentability are distinct.

Applicants attempt to draw analogy to *Enzo vs. Gen-Probe, U.S. State of Court of Appeals for the Federal Circuit*, for indicating that there are hundreds of subsequences of a deposited sequence which may also meet a claimed hybridization ratio, and for indicating that a deposited sequence is described by virtue of its having been deposited, and that various subsequences, mutations, and mixtures of those sequences are also described, and hold that question as an issue of fact (response, page 20, 1st full paragraph). However, the issue in *Enzo* and the instant rejection is not analogous. The hundreds of subsequences that may meet the claimed invention discussed in *Enzo*, and its various subsequences, mutations and mixtures, must still have the properties of the deposited sequence, not other properties or just a portion of the properties. If the subsequences, mutations and mixtures did not have the same properties, they would not have any relation to the deposited sequence. Applicants continue the analogy to *Enzo*, arguing that the issue of whether progeny as now claimed satisfies the issue of written description is also an issue of fact. Applicants argue that one of ordinary skill would know if PH3PG were utilized in a breeding program by looking at the breeding records, and that routine molecular techniques can be used to verify whether PH3PG is within the pedigree of a line (response, page 21, 1st full paragraph). In the instant rejection, the progeny do not express all of the morphological and physiological traits of PH3PG, unless it is a product of a self-cross. Further, determination that PH3PG is an ancestor of a plant does not provide sufficient

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description of all of the morphological and physiological traits of that plant. Furthermore, the originally filed specification does not describe any molecular determinants that one would need to identify any genetic material as having been derived from PH3PG or to verify that PH3PG is within its pedigree. No description has been provided concerning molecular markers that are unique to the PH3PG genome.

Applicants argue that traits and linkage groups present in PH3PG will be retained in progeny that are within one breeding cross of PH3PG, and that characterization of progeny of PH3PG is a clear and acceptable means of identification (response, paragraph bridging pages 21-22). However, the traits governed by the linkage groups are not described. Further, the genes and gene products inherited by the claimed progeny from PH3PG will be affected by the genes or their products inherited from the other parent. Applicants argue that royalties from lines developed through the use of inbreds are retained by universities and companies that license inbred maize (response, paragraph bridging pages 21-22). However, licensors pay royalties to use the licensed inbred, not the product progeny. Applicants argue that by limiting the progeny to one breeding cross away from PH3PG and limiting the progeny to those that contain at least 50% of their genetics from PH3PG, that the Examiner's concerns are addressed (response, page 22, 2nd full paragraph). However, the knowledge that the progeny contain at least 50% of the "genetics" of PH3PG does not describe the traits expressed by those genetics, or how traits are affected by the genes inherited from the other parent.

Regarding claims 37-39, Applicant argues that the claims are directed to growing out F1 hybrid in which PH3PG is a parent and searching for PH3PG inbred seed, and that the claim is described in the specification on pages 5-6 (response, page 15, 2nd full paragraph). However, as

discussed above, the claims are included in the rejection because the method encompasses the use of products that are not described.

8. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a **new matter** rejection.

There is no descriptive support in the specification for the recitation "at least 50% genetic contribution from".

9. Claims 37-39 and 52-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 09 October 2002 for claims 18-20 and 47-49 under item 11. Applicants traverse the rejection in the paper submitted 10 March 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicants argue that Hunsberger et al. succeeded in incorporating a gene into petunia plants of different genetic backgrounds, and cite Hallauer et al. for teaching that for single gene traits, the backcross method is relatively easy to manage (response, paragraph bridging pages 24-25). However, Hunsberger et al. teach failures as well. Hallauer et al. do not teach that the

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genome of the recurrent parent can be completely recovered in only two crosses. Further, the claims do not indicate that single genes are backcrossed, but rather a trait is backcrossed, which encompasses all traits, regardless of complexity. Applicants argue that Kraft et al. do not teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising single gene conversions, and that the teachings of the reference are in relation to sugar beet, not maize (response, page 25, 1st full paragraph). However, Kraft et al. do teach the unpredictability inherent in the construction of genetic maps based upon molecular marker data, which counters Applicant's assertions that such maps may be constructed here.

Applicants also argue that the concept of an essentially derived variety was introduced into the 1991 Act of the UPOV convention, and that such varieties may be obtained by backcrossing (response, page 25, 2nd full paragraph). However, the USPTO is not subject to UPOV Convention rules, as Article 35(2) of the 1991 UPOV Convention Act ensures that the United States adheres to its patent system.

Applicants argue that Eshed et al. teach that selected QTL in maize did not show a less than additive trend (response, page 26, 1st full paragraph). However, it is not clear that this is true for all loci. Further, as discussed above, Openshaw et al. teach that two backcross generations recover only 87.5% of the recurrent parent genome.

Further, the issue concerns whether a single gene or single trait alone can be brought into the inbred by backcross conversion. In the outcross, different alleles at all loci are introduced. During the backcross, particular traits are selected for. The specification only teaches a small number of the myriad traits of the deposited line. The other traits at the multitude of other alleles

are not taught. Applicants then fail to provide guidance from plants derived from the deposited inbred line by backcross conversion, that have only a single gene or single trait difference.

Claims 37-39 have been included in this rejection, as the specification does not teach how one would distinguish the inbred plants from all of the other types of hybrid plants in the collection. The specification does not teach any phenotypic or genotypic information for any of the hybrids, nor does the specification as originally filed teach any genotypic information for PH3PG. In the absence of further guidance, undue experimentation would be required by one skilled in the art to distinguish PH3PG plants from all of the different hybrids plants grown from the collection of seed.

10. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of transforming PH3PG when the transgene is known in the art and whose effect when expressed in transformed plants is known, does not reasonably provide enablement for the claimed method with all transgenes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claim is broadly drawn towards a method of developing a transgenic PH3PG maize plant wherein inbred maize plant PH3PG is transformed with any transgene.

The specification teaches morphological and physiological traits expressed by inbred maize plant PH3PG, and that PH3PG seed has been deposited with the ATCC under Accession No. PTA-4526 (Table 1; page 44). The specification indicates that PH3PG may be transformed

with transgene(s), and provides examples of some particular transgenes known in the art (page 21, line 34 to page 34, line 2).

However, the specification does not enable transforming maize plant PH3PG with all transgenes. As broadly interpreted, the method encompasses introducing any type of transgene into PH3PG, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g. a DNA sequence). Further, if the effect of transgene expression in PH3PG is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed PH3PG are unknown. The specification does not teach one how to use a transformed PH3PG plant if all of the morphological and physiological traits of PH3PG are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Summary

11. Claims 1, 2, 4, 5, 7, 21, 23, 24, 26, 27, and 40 are allowed. Claim 8 is objected to. Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 6, 25, and 52-59 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



ASHWIN D. MEHTA, PH.D.
PATENT EXAMINER

July 10, 2003